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EXAMINER

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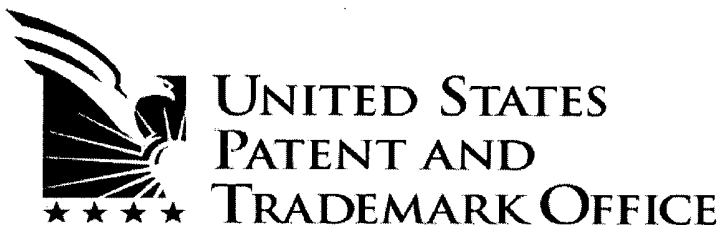
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Please find below and/or attached an Office communication concerning this application or proceeding.



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In re Application of :
Gray et al :
Serial No.: 09/509,165 : Decision on Petition
Filing Date: 12 June 2000 :
Attorney Docket No. 27866/34810 :

This letter is in response to the Petition filed 30 October 2003, requesting withdrawal of the restriction requirement and/or withdrawal of the finality of the Office action mailed 27 August 2003. The delay in acting upon this petition is regretted.

BACKGROUND

This application is a national stage filing under 35 USC 371 of PCT/US98/20270. On 17 May 2002, the Examiner restricted claims 1-14 and 26-37 into 12 Groups as follows.

- Group I, claims 1-5, drawn to a purified polypeptide.
- Group II, claims 1, 6-9, drawn to a polynucleotide, a vector comprising the polypeptide, a host cell comprising the polypeptide and a method for producing a polypeptide with the host cells.
- Group III, claims 10-11, drawn to an antibody that specifically binds to a MDC polypeptide and a hybridoma cell line producing the antibody.
- Group IV, claim 12, drawn to a kit for assaying MDC polypeptide.
- Group V, claim 13, drawn to a method for identifying a modulator for binding MDC and a MDC receptor.

- Group VI, claim 14, drawn to another method for identifying a modulator of binding MDC and a MDC receptor.
- Group VII, claims 26, 30-31 drawn to a method of palliating an allergic reaction in a mammalian subject.
- Group VIII, claim 27, drawn to a method for treating a disease state.
- Group IX, claim 28, drawn to a method for treating lupus erythematosus.
- Group X, claim 29, drawn to a method of treating a disease by activation, chemotaxis or proliferation of cells expressing CCR4+ receptor.
- Group XI, claims 32-33, drawn to a vaccine composition and method of using the composition to stimulate an immune response.
- Group XII, claims 34-37, drawn to method of screening a patient suspected of suffering from or undergoing treatment.

On 20 September 2002, Applicants elected Group VII with traverse.

On 3 December 2002, the examiner considered the traversal and made the restriction requirement final. Claims 1-14, 27-29 and 32-37 were withdrawn from consideration as being directed to non-elected inventions. Claims 26, 30 and 31 were rejected under 35 USC 112, first and second paragraph. Claims 26 and 30 were also rejected under 35 USC 102(b) as being anticipated by Wells et al.

On 3 June 2003, Applicants filed an amendment to add claims 38-43 and a response to the Office action. On 27 August 2003, the Office mailed a Final Office action, which withdrew claims 40-43 from consideration as being directed to a non-elected invention. Claims 26 and 30 continued to be rejected under 35 USC 112, first paragraph. Claims 38 and 39 were indicated as allowable.

On 30 October 2003, this petition was filed.

DISCUSSION

The file record, Restriction Requirement and the petition have been considered carefully.

The Unity of Invention determination, while essentially correct, contained the following errors, which are being corrected now to more clearly delineate between inventions.

Group II corresponds to claim 6-9. Claim 1 recites polypeptides and should not have been placed in Group II, which is drawn to polynucleotides.

Claims 13 and 14 differ only in respect to the source of cells used in step (a). Because the method steps have not been distinguished under PCT Rules, Groups V and VI are rejoined.

The vaccine composition of Group XI, (claim 32) comprising the polypeptide, has been rejoined with the polypeptide of Group I. Group XI remains directed to the method of using the polypeptide (claim 33).

While the examiner did set forth additional restrictions within Groups I, II and IV, Applicants are correct in noting that no additional restriction was required for the election of Group VII.

The Final Office action erred in providing appropriate reasoning for withdrawing the claims. The criteria of "independent and distinctness" relate to restriction practice under 35 USC 121. Because this is a national stage application filed under 35 USC 371, the examiner should have considered PCT unity of invention when determining whether the claims should have been examined or withdrawn. PCT Rule 13.2 requires (1) that the groups be linked by a same or corresponding technical feature and (2) that the technical feature defines a contribution over the prior art. Since the Examiner has determined independent claim 26 is free of the prior art, (see Final Office action) any dependent claims which are narrower in scope than claim 26 would necessarily share the same or corresponding special technical feature with the independent claim.

Moreover, the final Office action did not clearly set forth which claims were being withdrawn. The final Office action stated that claims 40, 42 and 43 were not considered and then stated that claims 40-43 were withdrawn.

Claims 26 and 30, which have been under examination as elected Group VII, are set forth below.

26. A method of palliating an allergic reaction in a mammalian subject, comprising the steps of identifying a mammalian subject in need of treatment for an allergic reaction that is characterized by eosinophil accumulation, and administering to said mammalian subject a composition comprising an MDC antagonist compound or TARC antagonist compound in an amount effective to palliate the allergic reaction.

Claim 30, also under examination and depending upon claim 26, further defined the antagonist as

- (a) a polypeptide fragment analog of a vertebrate MDC that inhibits MDC activation of an MDC receptor;
- (b) an antibody that specifically binds a vertebrate MDC polypeptide;
- (c) an MDC antagonist according to claim 20,
- (d) a polypeptide capable of binding to a vertebrate MDC polypeptide and comprising an antigen-binding fragment of an anti-MDC antibody;
- (e) a polypeptide comprising the C- C chemokine receptor 4 (CCR4) amino acid sequence set forth in SEQ ID NO: 34 or comprising a continuous fragment thereof that is capable of binding to MDC; and
- (f) combinations of (a)-(e).

New claims 40-43 are set forth below.

40. (New) The method according to claim 26 wherein the MDC antagonist compound comprises a polypeptide selected from the group consisting of
N-terminal deletion polypeptide mutants of amino acids 1-69 of SEQ ID NO: 2 in which 1-11 residues have been deleted,
a polypeptide having the amino acid sequence of SEQ ID NO: 30 ("MDC (n+1)"),
N-terminal addition polypeptide mutants of amino acids 1-69 of SEQ ID NO: 2 in which at least one amino acid residue is added,
a polypeptide having the amino acid sequence of SEQ ID NO: 31 ("MDC-yl"),
a polypeptide having the amino acid sequence of SEQ ID NO: 32 ("MDC-eyfy"), and MDC(delta)Pro2 polypeptides.
41. (New) The method according to claim 26 wherein the MDC antagonist compound comprises a polypeptide having the amino acid sequence of SEQ ID NO: 25.
42. (New) A method of palliating an allergic reaction in a mammalian subject, comprising the steps of:
identifying a mammalian subject in need of treatment for an allergic reaction that is characterized by eosinophil accumulation, and
administering to said mammalian subject a composition comprising a TARC antagonist compound in an amount effective to palliate the allergic reaction.
43. (New) A method according to claim 42 wherein the TARC antagonist compound is selected from the group consisting of:
(a) an antibody that specifically binds a vertebrate TARC polypeptide;
(b) a polypeptide that specifically binds a vertebrate TARC polypeptide and comprises an antigen-binding fragment of an anti-TARC antibody;
(c) a polypeptide comprising the C-C chemokine receptor 4 (CCR4) amino acid sequence set forth in SEQ ID NO: 34 or comprising a continuous fragment thereof that specifically binds TARC; and
(d) combinations of (a)-(c).

The Unity of Invention determination did not require a further restriction within Group VII. The first Office action on the merits examined the full scope of claim 26, as evidenced by remarks concerning TARC antagonists in the enablement rejection (page 5, second full paragraph). Newly added dependent claims 40-43 are properly narrower in scope than independent claim 26. The examiner erred in relying upon US-style restriction requirement reasoning (independent and distinct) criteria for withdrawing these claims from examination, since this application is entitled to PCT Rules. PCT Rule 13.2 states that unity of invention exists when the shared technical feature makes a contribution over the prior art. The Final Office action contains no prior art rejections on the claims, indicating that the claims share a special technical feature.

Because the scope of claims 40-43 falls within the scope of elected claim 26, because the subject matter of claim 26 has already been examined in full, because no further restriction was made within elected Group VII, and because the dependent claims must necessarily share a special technical feature when the independent claim is free of the prior art, claims 40-43 are rejoined with the elected invention.

DECISION

The petition is **GRANTED** for the reasons set forth above. In view of this decision, finality of the Office action mailed 27 August 2003 must be withdrawn. Claims 40-43 have been rejoined to the elected invention.

The application is being forwarded to the examiner for full consideration of the amendment and response filed 3 June 2003 and 30 October 2003 and completion of an Office action on the elected invention, claims 26, 30-31 and 38-43.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA 22313-1450 or by telephone at (703) 308-7553 or by facsimile transmission at (703) 305-7230.



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